

REMARKS

This is in response to the final Official Action of May 18, 2009. Applicants traverse the outstanding rejections. The prior art rejections fail to provide a teaching or suggestion for selection of an express element of the claims, and they fail to make a *prima facie* case of obviousness. Applicants request further examination, and reconsideration and withdrawal of the rejections.

Amendments to the Claims

Claim 1 is amended to state that Gilsonite oil is the major proportion ingredient of the pharmaceutical composition. Specification, ¶ 0015, ("In some formulations the Gilsonite oil component can be present as the major proportion ingredient (possibly even the only ingredient besides the bioactive agent) and thus serve the functions of both the penetration enhancer and carrier or diluent."). Thus, claim 1 is directed to formulations wherein Gilsonite oil constitutes greater than 50% of the composition.

New claim 41 is added reciting a pharmaceutical composition consisting only of the recited bioactive ingredients and Gilsonite oil. As claimed, those compositions contain only the bioactive agent and Gilsonite oil. Specification, ¶ 0015.

New claims 42 and 43 are supported by the specification at ¶ 0017 ("The Gilsonite oil-bioactive agent component and the Gilsonite oil-carrier component can each be formulated as described above, then these two components can be mixed or formulated in a weight ratio ..., preferably about 10:90 to about 90:10 and more preferably about 20:80 to about 80:20.").

Prior Art

Applicants traverse the prior art rejections. The rejections fail to provide a teaching or suggestion of the invention as claimed; and, in particular, fail to provide a teaching or suggestion of an express element of the claims, i.e., Gilsonite oil.

Claim 1 is rejected over Orlowski in view of Friedman. The rejection fails to make a prima facie case.

The scope of claim 1, properly construed, excludes ingredients that do not materially affect the basic and novel characteristics of the claimed subject matter. MPEP 2111.03. Thus, claim 1 would eliminate from its plain meaning substantial additional ingredients such as mineral oil carriers as required in Orlowski.

Throughout the specification, applicants clearly expressed an intention that the methods involve use of pharmaceutical compositions wherein the only ingredients material to the basic and novel characteristics of the formulations were a bioactive agent and Gilsonite oil. *E.g.*, ¶¶ 0015, 0017, 0019-22, 0045. However, applicants also made it quite clear that other optional ingredients could be included. Thus, applicants expressed an intention that the claimed formulation could include a bioactive agent and Gilsonite oil as the only ingredients materially affecting the basic and novel properties, but that other benign or inactive ingredients could be included as well. Accordingly, applicants have demonstrated possession of the claimed invention, and provided written support for the invention of claim 1 wherein the phrase "consisting essentially of" is supported and properly accorded the more restrictive interpretation as a middle ground between "comprises" and "consisting of." MPEP 2111.03. Applicants' use of the intermediate transition phrase "consisting essentially of" is supported by the specification.

Further, the transition phrase "consisting essentially of" is properly accorded the more restrictive intermediate scope between "comprising" and "consisting of." For purposes of searching for and applying prior art, the construction of that phrase as equivalent of "comprising" is only appropriate "absent a clear indication in the specification or claims of what the basic and novel characteristics actually are." MPEP 2111.03. Here, there is such a clear indication. As demonstrated above, applicants expressed a clear intention of claiming methods of treatment using pharmaceutical compositions wherein the only ingredients are a bioactive agent for treating nail disease and Gilsonite oil, and that Gilsonite oil may serve as both the penetration enhancing agent and as carrier; but that other, merely optional, inactive and inconsequential additives may be included. Applicants also expressly stated an intention of claiming formulations wherein the Gilsonite oil is the "major proportion ingredient." Specification, ¶0015. Thus, applicants expressed an appreciation of, and demonstrated possession of, a pharmaceutical formulation including a bioactive agent and Gilsonite oil, and optional additional, but generally inconsequential, extraneous ingredients.

The appropriate claim scope of claim 1 eliminates the other components of Gilsonite that are necessarily included in Orlowski's suspension of crushed Gilsonite in mineral oil. Orlowski provides no information about what the various components of Gilsonite do, nor does it address whether any of those components must be included or could be eliminated. Additionally, Orlowski is silent as to the existence or utility of Gilsonite oil, and does not provide any teaching or suggestion about what any of the other component parts of Gilsonite do or don't do. Orlowski does not provide any teaching or suggestion leading any one skilled in the art to isolate,

separate, or utilize any of the various discrete components of Gilsonite. Thus, even if one knew of the existence of an oil component of Gilsonite, Orlowski provides no teaching or suggestion that such a component has any beneficial properties.

Finally, the present amendment of claim 1 further distinguishes Orlowski. Claim 1 is hereby amended to recite that the Gilsonite oil is the major proportion ingredient. As such, the claim scope is restricted to methods using those formulations wherein Gilsonite oil constitutes greater than 50% by weight of the formulation. As shown by the Declaration of David Fisher (2/9/2009, "Fisher II"), Gilsonite contains only very small quantities of Gilsonite oil. As Gilsonite oil is most broadly defined by applicants, Gilsonite contains only about 5 wt. % Gilsonite oil. Fisher II, ¶ 4. More refined fractions, such as those claimed here, are present in Gilsonite at only about 0.1 wt. %. Fisher II, ¶ 5. Thus, it would not be possible for a composition as described in Orlowski (i.e., Gilsonite suspended in mineral oil) to be constituted in such a way as to arrive at a formulation wherein the Gilsonite oil is a major proportion ingredient of the formulation. Even ignoring the requisite carrier, such as mineral oil, the Fisher Declaration shows that the suspension could be no more than about 5 wt. %.

The teaching of Orlowski further goes against the claimed invention. Orlowski describes a composition wherein the entirety of the Gilsonite in the formulation is only about 6.25%, other constituents constitute only about 4%, and the remainder is the mineral oil carrier. Thus, Orlowski teaches a formulation wherein the mineral oil carrier constitutes about 90% (volume) of the formulation. Even in its broadest definition, Gilsonite oil is present in only about 5 wt. % of Gilsonite. As such, Gilsonite oil in the formulation of Orlowski would constitute only about 0.3% of the

formulation. Orlowski describes a formulation that could not have given rise to the quantities of Gilsonite oil as now claimed. Fisher II, ¶ 4-5. As discussed above, it could have produced a composition having no more than about 0.3 wt % of Gilsonite oil (and no more than 0.006 wt % of the Gilsonite oil of claims 37-40 and 42-43).

Nor does Orlowski teach or suggest which of the various component parts of Gilsonite are responsible for any advantageous property, much less the particular property relied upon by applicants. Indeed, Orlowski does not even suggest that Gilsonite acts as a penetration enhancer or have any other independent therapeutic enhancing effect. Orlowski merely states that Gilsonite "acts as a sealant for sealing in the soybean oil into the nail of the human body and is substantially waterproof." Orlowski at p. 6; *see also* p. 5 ("The composition of this invention comprises ... a natural resin, namely gilsonite, *which seals the soybean oil into the nail and cuticle*, ... and a carrier such as mineral oil which is used as a dilatant and carrier for the ingredients of the composition." emphasis added). Thus, according to Orlowski, the Gilsonite acts as nothing more than a protective sealant covering the soybean oil.

Nothing in Orlowski teaches or suggests that Gilsonite, or any component part thereof, could function as a penetration enhancing agent in a pharmaceutical composition. Even if one were motivated by Orlowski to look for a specific component of Gilsonite to better serve the purpose to which Orlowski puts Gilsonite, the search would focus on materials that serve as optimal sealants, not penetration enhancers. Thus, it is unlikely that such a search would have produced the claimed invention.

Friedman does not cure the deficiencies of Orlowski. While Friedman may disclose the use of hydrocortisone in a nail treating composition; it does not provide

any teaching or suggestion of using Gilsonite oil in any such formulation. As taught by Forrest (USPN 1,573,765), Gilsonite is chemically very complex; but the complex material can be broken up or decomposed such that there are obtained and segregated or collected separately a number of different products and classes of products. Forrest, p. 2, lines 36-50. The gaseous portion may be used as a fuel or illuminant; but it is of considerable complexity, and can be made to yield nitrogenous and other useful products without impairment of its combustive utility. Forrest, p. 2, lines 55-60. Furthermore, the "liquid products present the utmost variety and complexity...." Forrest, p. 2, lines 69-70. And that the "crude oil distillate is a highly complex material, capable of fractionation to an almost unlimited extent." Forrest, p. 6, lines 12-15. Thus, the art recognized that Gilsonite is chemically very complex, that there are many components to it, and that those components have diverse properties.

Further, Forrest states that "[T]he effect of the progressive heating of the gilsonite is to gradually break it up and decompose it chemically." Forrest, p. 3, lines 33-36. Further, "the coming off of particular products depends on the stability under heat of the highly complex chemical combinations amongst the constituents of gilsonite, as well as the boiling points of the products themselves. The matter is further complicated, no doubt, by the liberation, formation, and decomposition of intermediate products, both in the body of liquid and in the body of vapor." Forrest, p. 3, lines 44-54. Thus, Forrest teaches that the fractionation process itself chemically changes many of the components of the chemically complex mixture known as Gilsonite, and that many of those components are decomposed or chemically altered into a new chemical entity.

One skilled in the art would have understood that Gilsonite oil is not the equivalent of Gilsonite, and that the various component parts are subject to potentially unlimited fractionation. Thus, Orlowski, alone or in combination with Friedman, would not have taught or suggested the claimed invention.

Claims 37-40 are rejected over Orlowski in view of Friedman and Smith. Applicants traverse the rejection.

As shown above, Orlowski fails to teach or suggest the claimed invention, alone or in combination with Friedman. Smith fails to remedy the deficiencies of those references.

It is asserted that Smith "teaches cosmetic composition comprising oils that soften the skin and provide degree of barrier against the environmental irritants, the oils preferred to have viscosity between 35-70 cps and specific gravity between 0.8 and 0.9."

The references are from non-analogous arts. Even if that were not the case, Smith fails to remedy the deficiencies of Orlowski and Friedman, and thus the combination fails to make a prima facie case of obviousness.

Smith is non-analogous art relative to Orlowski and Friedman. Orlowski is directed to a pharmaceutical composition in the form of an emulsion that can be applied to nails comprising soybean oil, cresylic acid, and Gilsonite, suspended in mineral oil. Friedman teaches the use of hydrocortisone in a nail treating composition. Smith, however, is directed to a dispensing and applicator device having various cover sheets and a support sheet. The device is used for containing, dispensing, and applying two or more substances such as solids such as powders or granules, and/or flowable substances such as gels, dispersions, or solutions. Col. 3-

4. The system is particularly well-adapted to contain, preserve, and to sequentially or simultaneously deliver two or more incompatible active ingredients.

The instant composition incorporates no such system, nor is it devoted or intended to deliver two or more incompatible active agents. Moreover, the Smith reference is silent as to the various uses or properties of Gilsonite, and is likewise silent as to what properties of Gilsonite might be retained in the various fractions or distillates of Gilsonite.

Although Smith does discuss the possible use of emollient oils in those devices, there is no mention or suggestion of the use of Gilsonite or any of the constituent parts thereof. Nor is there any suggestion in Smith as to what advantageous properties Gilsonite might afford, either in the Smith system or any other; and there is no suggestion as which of the various and complex component parts of Gilsonite might afford any such advantages. Further, one skilled in the art would have understood that such emollients and oils are described as being useful in the peculiar multi-component applicator devices disclosed in Smith, which bear no resemblance whatsoever to the methods of administration and formulations of the instant claims.

It is asserted - without any support - that one skilled in the art would look to Smith for its teaching of the use of certain emollients based upon their viscosity and specific gravity. One skilled in the art would have immediately appreciated that there is a great deal more to the selection of such ingredients, particularly in a pharmaceutical device or formulation, than merely the viscosity and/or specific gravity of a composition. One skilled in the art would have understood that there are many factors to be considered in the selection of such materials, including the

agent's toxicity, potentially adverse reactions, potential interactions with the active agents and/or other excipients, and the like. Thus, to suggest that all oils or emollients having a common range of viscosity and/or specific gravity would be equally useful in a pharmaceutical composition is a gross mischaracterization of the art, and is wholly unsupported.

While it might be true that one might look to such properties among others in generally acknowledged pharmaceutically acceptable emollients, there has been no showing that Gilsonite oil was among that class prior to the instant invention. The most that can be said, based upon the instant record, is that a reference teaches a pharmaceutical emulsion having at most about 0.006% of the claimed Gilsonite oil, which is a far cry from the claimed formulations wherein the Gilsonite oil comprises as much as about 90 wt % of the formulation.

Additionally, the proposition ignores the penetration enhancing effect discovered by applicants, which is neither taught nor suggested anywhere in any of the cited references. Accordingly, the rejection and cited references fail to provide a reasoned basis for combining the two references in the first instance. Even if one were to combine the two references, there is no showing that a skilled worker would have extracted the various elements of those references necessary to arrive at the presently claimed invention. Further, even if one were to extract those various elements, there has been no showing of any well reasoned basis for combining those elements in such a way as would have produced the presently claimed invention. Accordingly, there is no prima facie showing of obviousness. Applicants request further examination, and reconsideration and withdrawal of all outstanding rejections.

In view of the foregoing amendments and remarks, applicants respectfully request reconsideration and withdrawal of all outstanding rejections. Applicants submit that the claims are now in condition for allowance, and respectfully request formal notification to that effect. If, however, the Examiner perceives any impediments to such a notice of allowability, whether substantive or formal, the Examiner is encouraged to call Applicants' attorney at the number provided below. Such informal communication will expedite examination and disposition of this case.

Respectfully submitted,

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